REMARKS

This amendment is being filed in response to the non-final Office Action dated October 27, 2008 (hereinafter "the Office Action").

Applicants have amended claims 1, 12, 22, 28, 37 and 45 to incorporate subject matter recited in claim 51. Claim 51 have been canceled without prejudice or disclaimer.

Now pending in the application are claims 1-50. Claims 37-50 were withdrawn from further consideration in response to the Examiner's restriction requirement dated June 30, 2006. Amongst claims 1-36, claims 1, 12, 22 and 28 are independent.

I. Summary of Rejections

In the Office Action:

claims 1-36 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter;

claims 1, 12-19, 21, 24, 28 and 31 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,882,940 to Potts, *et al.* (hereinafter "Potts"); and

claims 1-30, 32-36 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over "Mathematical Simulation and Analysis of Cellular Metabolism and Regulation" by I. Goryanin, *et al.*, Bioinfomatics, 1999, Vol. 15, No. 9, pp.749-758 (hereinafter "Goryanin") in view of "Tissue Microarray (TMA) Technology: Miniaturized Pathology Archives for High-throughput *in situ* Studies" by L. Bubendorf, *et al.*, Journal of Pathology, 2001, Vol. 195, pp.72-79 (hereinafter "Bubendorf").

These rejections will be discussed separately below.

II. Claim Rejections under 35 U.S.C. §101

A. Tangible Result

In the Office Action, the Examiner rejected claims 1-36 under 35 U.S.C. §101 claiming that "[t]he limitation of saving the model in a storage is not a tangible result as nothing is communicated in a user readable format such that it is useful to one skilled in the art." (*See* the Office Action, page 4).

Applicants note that the United States Court of Appeals for the Federal Circuit has recently discarded the "useful, concrete, and tangible result" test for determining patentable subject matter under 35 U.S.C. §101. *In re Bilski*, Case 2007-1130 (Fed. 2008) (*en banc*). Therefore, Applicants respectfully urge that the Examiner reconsider and withdraw the above 35 U.S.C. §101 rejection of claims 1-36.

B. Particular Apparatus or Machine

In the Office Action, the Examiner rejected claims 12-27 under 35 U.S.C. §101 claiming that "the method steps that are critical to the invention are 'not limited to a particular apparatus or machine.'" (*See* the Office Action, page 4). Applicants respectfully disagree.

Applicants respectfully submit that claims 12-27 are tied to a particular apparatus or machine. Claims 12-27 are tied to *an in situ experimental device* on which an ongoing in situ experiment of the biological process is conducted. The in situ experimental device on which an ongoing in situ experiment of the biological process is conducted is a particular apparatus or machine. Therefore, Applicants respectfully urge that claims 12-27 are directed to statutory subject matter, and respectfully request reconsideration and withdrawal of the above 35 U.S.C. §101 rejection of claims 12-27.

III. Claim Rejections under 35 U.S.C. §102(e)

In the Office Action, the Examiner rejected claims 1, 12-19, 21, 24, 28 and 31 under 35 U.S.C. §102(e) as being anticipated by Potts (*See* the Office Action, page 6). Applicants respectfully traverse this rejection.

A. Claim 1

Claim 1 recites:

> 1. A computer-readable medium holding instructions executable in a computing device, the medium comprising one or more instructions for:
>
> ***generating a result from executing a block diagram model of a biological process with a simulation engine***;
>
> gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted;
>
> ***comparing the generated result to the data gathered from the experimental device with an analysis environment that is in communication with the simulation engine***; and
>
> ***modifying the model of the biological process based on the comparison to correct the model of the biological process***.

Applicants respectfully urge that Potts does not disclose or suggest at least the following features of claim 1: ***generating a result from executing a block diagram model of a biological process with a simulation engine***; ***comparing the generated result to the data gathered from the experimental device***; and ***modifying the model of the biological process based on the comparison to correct the model of the biological process***.

With regards to ***generating a result from executing a block diagram model of a biological process with a simulation engine***, Potts fails to disclose executing a block diagram model of a biological process. Nowhere does Potts disclose or suggest a block diagram model of a biological process.

With regards to ***comparing the generated result to the data gathered from the experimental device***, Potts fails to disclose or suggest this claimed feature as well. In the Office Action, the Examiner alleges that comparing skin conductance with a threshold value, described in Potts in claims 1 and 25, and correlating blood glucose measurements with "out of sample" predictions, described in Potts at column 8, lines 45-67, teaches the Applicants' claimed ***comparing***

the generated result to the data gathered from the experimental device. Applicants respectfully disagree.

Nowhere does Potts disclose or suggest that a result generated from executing a block diagram model of a biological process is compared to the data gathered from the experimental device. There is no disclosure in Potts of comparing a result generated from executing a block diagram model of a biological process with a certain value. Therefore, Potts does not disclose or suggest Applicants' claimed ***comparing the generated result to the data gathered from the experimental device***.

With regards to ***modifying the model of the biological process based on the comparison to correct the model of the biological process***, Potts fails to disclose this feature of Applicants' claim 1. In the Office Action, the Examiner alleges that Potts discloses "training" a prediction algorithm and that this disclosure teaches Applicants' claimed ***modifying the model of the biological process based on the comparison to correct the model of the biological process***. Applicants respectfully disagree.

Nowhere does Potts disclose or suggest modifying a block diagram model of a biological process. In Potts, the prediction algorithm is an algorithm that is used to predict the GlucoWatch biographer system values. See Potts, columns 23-27. The prediction algorithm described in Potts is not a block diagram model of a biological process. Therefore, Potts GlucoWatch system does not disclose or suggest Applicants' claimed ***modifying the model of the biological process based on the comparison to correct the model of the biological process***.

For at least the reasons set forth above, Applicants respectfully urge that Potts does not disclose or suggest Applicants' claim 1. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 1 be withdrawn.

B. Claim 12

Claim 12 recites:

> 12. A method for modifying a model of a biological process, the method comprising:

accessing a block diagram model of the biological process;

generating a result from an execution of the model of the biological process;

gathering data directly from an in situ experimental device on which an ongoing in situ experiment is conducted;

comparing the generated result to the data gathered from the ongoing in situ experiment; and

modifying the model of the biological process based on the comparison to correct the model of the biological process.

As discussed above with respect to claim 1, Potts fails to disclose or suggest ***generating a result from an execution of the model of the biological process***; ***comparing the generated result to the data gathered from the experimental device***; and ***modifying the model of the biological process based on the comparison to correct the model of the biological process***. These features are also present in claim 12. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 12. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 12 be withdrawn.

C. Claims 13-19 and 21

Claims 13-19 and 21 depend on claim 12 and, as such, incorporate all of the features of claim 12. For at least the reasons set forth above with respect to claim 12, Applicants respectfully urge that Potts fails to disclose or suggest all of the features of claims 13-19, and 21. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(e) rejection of claims 13-19 and 21.

D. Claim 24

As discussed above with respect to claim 1, Potts fails to disclose or suggest ***generating a result from an execution of the model of the biological process***; ***comparing the generated result to the data gathered from the experimental device***; and ***modifying the model of the biological process based on the comparison to correct the model of the biological process***.

These features are also present in claim 22. Claim 24 depends on claim 22 and, as such, incorporates all of the features of claim 22. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 24. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 24 be withdrawn.

E. Claim 28

Claim 28 recites:

> 28. A computer-readable medium holding instructions executable in a computing device, the instructions comprising one or more instructions for:
>
> ***generating a result from executing a block diagram model of a biological process***;
>
> gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted;
>
> ***comparing the result to the data gathered from the experimental device***; and
>
> ***modifying the model of the biological process based on the comparison***.

As discussed above with respect to claim 1, Potts fails to disclose or suggest ***generating a result from executing a block diagram model of a biological process***, ***comparing the generated result to the data gathered from the experimental device***, and ***modifying the model of the biological process based on the comparison to correct the model of the biological process***. These features are also present in claim 28. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 28. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 28 be withdrawn.

F. Claim 31

Claim 31 depends on claim 28 and, as such, incorporates all of the features of claim 28. For at least the reasons set forth above with respect to claim 28, Applicants urge that Potts fails to disclose all of the features of claim 31. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(e) rejection of claims 31.

IV. Claim Rejections under 35 U.S.C. §103(a)

In the Office Action, the Examiner rejected claims 1-30, 32-36 and 51 under 35 U.S.C. §103(a) as being unpatentable over Goryanin in view of Bubendorf (*See* the Office Action, page 9). Applicants respectfully traverse this rejection.

A. Claim 1

Applicants respectfully urge that Goryanin and Bubendorf, taken either alone or in any reasonable combination, do not disclose or suggest at least the following features of claim 1: ***generating a result from executing a block diagram model of a biological process with a simulation engine*** and ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***.

With regards to ***generating a result from executing a block diagram model of a biological process with a simulation engine***, Goryanin in combination with Bubendorf fails to disclose or suggest executing a block diagram model of a biological process.

In the Office Action, the Examiner noted that "[t]he model is presented using a block diagram [Fig. 1]." (*See* the Office Action, page 9). Fig. 1 of Goryanin depicts a block diagram of DBsolve 5.00 architecture. Nowhere does Goryanin disclose or suggest generating a result from executing a block diagram model of a biological process. There is no disclosure in Goryanin of a block diagram model of a biological process. Therefore, Goryanin fails to disclose or suggest Applicants' claimed ***generating a result from executing a block diagram model of a biological process with a simulation engine***.

Bubendorf is cited by the Examiner to provide teachings for an in situ experiment (*See* the Office Action, page 10). However, Bubendorf is silent about a block diagram model of a

biological process. Bubendorf does not disclose or suggest Applicants' claimed ***generating a result from executing a block diagram model of a biological process with a simulation engine***, which is present in claims 1 and 28. Although Bubendorf is combined with Goryanin, the combination does not disclose or suggest generating a result from executing a block diagram model of a biological process.

With regards to ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***, the combination of Goryanin and Bubendorf fails to disclose or suggest this claimed feature as well.

The Examiner recognizes that Goryanin fails to disclose or suggest the above claimed feature. (*See* the Office Action, page 10).

The Examiner also recognizes that Bubendorf fails to disclose or suggest an ongoing in situ experiment. (*See* the Office Action, page 10). The Examiner, however, asserts that "this limitation would have been obvious to one of ordinary skill in the art since they employ a computer assisted method," and "[t]he rationale would have been to increase the number of data analyzed to improve statistical results in a clinical setting [Introduction]." (*See* the Office Action, page 10). Applicants respectfully disagree.

In Applicants' claim 1, experimental data is directly gathered from an ongoing in situ experiment of a biological process so that a block diagram model of the biological process may be modified in real time. This feature is not obvious over Bubendorf, which only describes Tissue Microarray (TMA) technologies and in situ tissue analyses (*See* Bubendorf, Abstract). Although Bubendorf discusses the construction of a TMA for use in in situ studies, Bubendorf does not disclose or suggest Applicants' claimed ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***, which is present in claim 1. Bubendorf is silent about gathering data directly from an ongoing in situ experiment. Although Bubendorf is combined with Goryanin, the combination suggests, at most, that the TMA data may be entered by a user. The combination does not disclose or suggest gathering data directly from an ongoing in situ experiment.

For at least the reasons set forth above, Applicants urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of

Applicants' claim 1. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 1 be withdrawn.

B. Claims 2-11

Claims 2-11 depend on claim 1 and, as such, incorporate all of the features of claim 1. For at least the reasons set forth with respect to claim 1, Applicants respectfully urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest all of the features of claims 2-11. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claims 2-11 be withdrawn.

C. Claim 12

As discussed above with respect to claim 1, Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest ***generating a result from an execution of the model of the biological process***; and ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment is conducted***. These features are also present in claim 12. Thus, Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of Applicants' claim 12. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 12 be withdrawn.

D. Claims 13-21

Claims 13-21 depend on claim 12 and, as such, incorporate all of the features of claim 12. For at least the reasons set forth above with respect to claim 12, Applicants respectfully urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest all of the features of claims 13-21. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §103(a) rejection of claims 13-21.

E. Claim 22

As discussed above with respect to claim 1, Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest ***generating a result from an execution of the model of the biological process***; and ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***. These features are also present in claim 22. Thus, Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of Applicants' claim 22. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 22 be withdrawn.

F. Claims 23-27

Claims 23-27 depend on claim 22 and, as such, incorporate all of the features of claim 22. For at least the reasons set forth above with respect to claim 22, Applicants respectfully urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest all of the features of claims 23-27. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §103(a) rejection of claims 23-27.

G. Claim 28

As discussed above with respect to claim 1, Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest ***generating a result from executing a block diagram model of a biological process***, and ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***. These features are also present in claim 28. Thus, Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of Applicants' claim 28. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 28 be withdrawn.

H. Claims 29, 30 and 32-36

Claims 29, 30 and 32-36 depend on claim 28 and, as such, incorporate all of the features of claim 28. For at least the reasons set forth above with respect to claim 28, Applicants

respectfully urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, fail to disclose or suggest all of the features of claims 29, 30 and 32-36. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §103(a) rejection of claims 29, 30 and 32-36.

V. Conclusion

In view of the above comments, Applicants believe that the pending application is in condition for allowance and urges the Examiner to pass the claims to allowance. Should the Examiner feel that a teleconference would expedite the prosecution of this application, the Examiner is urged to contact the Applicant's attorney at (617) 227-7400.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080, under Order No. MWS-109RCE. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account.

Dated: January 7, 2009

Respectfully submitted,

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